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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,331	12/12/2001	Michael T. Milbocker	PRAXIS-5	9980
71095	7590	12/12/2007		
Promethean Surgical Devices c/o Francis H Kirkpatrick 3 Gill St #G Woburn, MA 01801			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			12/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/020,331	<b>Applicant(s)</b> MILBOCKER, MICHAEL T.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-14,17-30,40-42 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-14,17-30,40-42 and 44-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment, remarks and declaration under 37 CFR 1.132, all filed 9/20/07. Claims 1-3, 5, 17, 40-42, 44-46, 48, 51 and 52 are amended. Claims 1-3, 5-14, 17-30, 40-42 and 44-52 are pending.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 5-14, 17-30, 40-42 and 45-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

For claim 1, a functionality of a range of 1.5-8 is envisioned and not at least 1.5 and 3 for claim 2

For claim 17, free polyisocyanate of at least 1% is not envisioned at the time of filing. Applicant indicate support at paragraph [0052] of the published application, but paragraph [0052] supports greater than 1% and since at least 1% starts at 1% and greater than 1% is not 1%, the recitation is not envisioned by the original specification.

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For claims 45 and 51, "less than 5% un-reacted low molecular weight polyisocyanate is not envisioned. Paragraph [0067] of the published application envisions at least 1% unreacted polyisocyanate.

The above rejections may be overcome by removing the new matter.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (US 5,624,972).

Muller discloses polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition (column 3, lines 8-16) and the composition comprises at least two polyisocyanate compositions, one is low in NCO polyisocyanate and the other is high NCO polyisocyanate (abstract). Toluene diisocyanate (claim 6) and isophorone diisocyanate (column 6, line 45) are examples of polyisocyanates. The functionality of the polyisocyanate terminated polyol is between 2 and 8 with an excess of isocyanate composition (column 3, lines 8-16). Additionally, Muller discloses that the composition comprises at least one other free polyisocyanate composition (See column 6, lines 38-62). These polymeric compositions contain PO/EO units; in the random copolymer, the oxyethylene content is from 10-80% and 2-30% for block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25);

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80/20 EO/PO and 25/75 PO/EO are also used (column 9, lines 46, 47). Muller discloses a range of PO: EO polymers. For example, random copolymer having the oxyethylene content of from 10-80% and 2-30% for block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25) is disclosed; also, 80/20 EO/PO and 25/75 PO/EO are also used as disclosed in column 9, lines 46, 47.

The recitation in amended claim 1 that the functionality of the polyol is at least 1.5 and not more than 5% reads on a Muller's polyol where the functionality is between 2 and 8, with at least 1.5 reading on 2 and not more than 5% falling between 2 and 8%. Muller meets the limitations of claims 1-3 and 8.

#### ***Response to Arguments***

5. Applicant's arguments filed 09/20/07 have been fully considered but they are not persuasive.

6. Applicant has presented arguments on pages 16-23 with the arguments focusing on the fact that applicant's block copolymer contains 10-30% PO, with the remaining being EO, that is at the upper limit of 30% PO, the content of the EO for the inventive composition is 70% and at the lower end of 10% PO, the EO content is 90% so that applicant argues that there is more EO in the inventive composition than there is for Muller's block copolymer polyol that has 2-30% EO. Applicant further states that when Muller talks about 10-80% EO, Muller is referring to random copolymer and that because Muller mixes in random polymers with high PO content that the overall content of PO in the copolymer remains high at above 70%.

7. While the examiner agrees with applicant that Muller describes random and block copolymers for which the random is at 10-80% EO (column 4, line 67 to column 5, line 1) and

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block copolymer at 2-30%, and while the examiner has carefully considered the arguments and the content of the interview of 6/12/07, it is noted that applicant describes the block structure to be random or regular at paragraph [0034] of the published application and it is the only section of the instant specification that describes block structure of the inventive copolymer. Thus when the random copolymer of Muller is 10-80% EO, the Muller polymer meets the requirements of applicant's block copolymer so that this embodiment of Muller would not have higher PO content than the inventive copolymer. Thus taken into consideration of how the polymer is made in Muller according to applicant that results in a copolymer having 72% PO, the fact that applicant defines block copolymer as random and regular and Muller's disclosure of an embodiment in which random copolymer has from 10-80% EO cannot be ignored and it is for this reason that the block copolymer of the claims reads on the random copolymer of Muller. Furthermore, the claims are directed to product/composition and not to the process of making the product.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 5-7, 9-14, 17-30, 40-42 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 5,624,972). Please note that claims 49-52 were inadvertently omitted in the previous rejections.

Muller discloses polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition (column 3, lines 8-16) and the composition comprises at least two polyisocyanate compositions, one is low in NCO polyisocyanate and the other is high NCO polyisocyanate (abstract). Toluene diisocyanate (claim 6) and isophorone diisocyanate (column 6, line 45) are examples of polyisocyanates. The functionality of the polyisocyanate terminated polyol is between 2 and 8 with an excess of isocyanate composition (column 3, lines 8-16). Additionally, Muller discloses that the composition comprises at least one other free polyisocyanate composition (See column 6, lines 38-62). These polymeric compositions contain PO/EO units; in the random copolymer, the oxyethylene content is from 10-80% and 2-30% for block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25); 80/20 EO/PO and 25/75 PO/EO are also used (column 9, lines 46, 47). Muller discloses a range of PO: EO polymers. For example, random copolymer having the oxyethylene content of from 10-80% and 2-30% for block copolymers (column 4, line 67 to column 5 line 5; column 7, line 64 to column 8 line 25) is disclosed; also, 80/20 EO/PO and 25/75 PO/EO are also used as disclosed in column 9, lines 46, 47.

Muller provides polymeric compositions comprising isocyanate-terminated polymers and a polyisocyanate composition as is discussed above. Future intended use carries no patentable weight in a composition claim; and if the instant composition is applicable as a tissue adhesive, the composition of Muller should also be applicable as a tissue adhesive since Muller discloses

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polyol and polyisocyanate. Specifically, the random copolymer having 10-80% EO content (column 4, line 67 to column 5 line 1) suggests a PO content of about 20-90%. Thus while Muller does not specifically disclose the percent propylene oxide recited in claim 4, there is a suggestion for a broader range of 20-80% that overlaps the 10% at the lower end and encloses the 30% at the upper end. Muller suggests PO:EO copolymer that has a ratio of from 20-80% in the PO. There is thus a suggestion for the range recited in claim 4 and the declaration of Milbocker has not taken into account all the combinations of PO:EO disclosed in the Muller reference, and it could also be said that the ranges used in the declaration filed 2/23/06 also read on the ranges disclosed by the Muller reference.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Muller to device compositions comprising one or more polyols terminated with a polyisocyanate and free polyisocyanate. One having ordinary skill in the art would have been motivated to use the desired amounts of PO and EO as suggested by Muller that would be expected to result in a flexible polyisocyanate polymeric composition/adhesive having the inherent properties of the adhesive.

#### ***Response to Arguments***

10. Applicant's arguments filed 09/20/07 have been fully considered but they are not persuasive.

11. Here, the argument is also one that has the inventive polymer having a higher content of EO than that of Muller, that the mixture that is polymerized in Muller always had greater than 70% PO because small additions of high EO polymers do not reduce the high PO content. Block structure as gleaned from applicant's published specification at paragraph [0034] is



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random or regular such that the random copolymer disclosed by Muller to have 10-80% EO meets the requirement. Therefore, applicant's definition of block copolymer as random and regular and Muller's disclosure of an embodiment in which random copolymer has from 10-80% EO cannot be ignored and it is for this reason that the block copolymer of the claims reads on the random copolymer of Muller.

Claims 49-51: These claims were inadvertently omitted in the previous rejection and applicant's argument that even if these claims are part of the previous rejection, these claims would have been inventive over Muller for the reasons that the PO and EO content in the inventive block polymer is different from the PO and EO content in the Muller. However, as noted above, applicant's definition of block copolymer as random and regular and Muller's disclosure of an embodiment in which random copolymer has from 10-80% EO cannot be ignored and it is for this reason that the block copolymer of the claims reads on the random copolymer of Muller.

Declaration by Michael Milbocker under 37 CFR 1.132:

12. The declaration under 37 CFR 1.132 filed 09/20/07 is insufficient to overcome the rejection of claims 1-3, 5-14, 17-30, 40-42 and 44-52 based upon 35 USC 102 (b) and 35 USC 103(a) as set forth in the last Office action because: the claims are product claims and the declaration has not considered Muller's disclosure of random copolymer having 10-80% EO meeting applicant's description for block structure gleaned from paragraph [0034] of applicant's published application.

No claim is allowed.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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